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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,538	03/20/2001	Mary A. Reppy	2001/00005	9053

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	16

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,538	REPPY ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *20-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-46 are pending.

2. Claims 20-46 have been withdrawn from further consideration as being drawn to a non-elected invention. It is noted that Claims 20-46 "*may be canceled by the Examiner upon the allowance of the claims directed to the elected invention*" as indicated by applicant on page 2 (lines 2-3) of the respond in Paper No. 15.

3. Claims 1-19 are treated on the merit in this Office Action.

Withdrawn Rejections

4. The previous rejections 35 USC 112, second paragraph, for claims 1-19 have been withdrawn arguments.

Maintained Rejections

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

6. Claims 1-2 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Reichert et al. (*J. Am. Chem. Soc.*, **1995**, 117:829-830).

The presently claimed claims recite a method for detection of an analyte in a sample. The method comprise of contacting the sample with the three-dimensional array. The three-dimensional array comprise of a polydiacetylene backbone and a substrate, wherein the substrate has direct affinity for an analyte. The polydiacetylene of the array is in the non-fluorescent form.

Reichert et al. disclosed a method of detecting influenza virus (analyte) with functionalized polydiacetylene liposomes (three-dimensional array) (pg. 829, left col., lines 20-27). The functionalized polydiacetylene liposome incorporates both the sialic acid ligand (substrate) for viral binding and the diacetylenic functionality, which is the conjugated backbone of alternating double and triple bonds (pg. 829, left col., lines 29-33), in the hydrocarbon chain for polymerization (pg. 829, right col., lines 1-3). The influenza virus is added to the liposomes in PBS buffer (contacting step), the solution immediately changes to a pink or orange color (the polydiacetylene of the array in a non-fluorescent form) (pg. 829, right col., lines 30-32). These color changes are readily visible with the naked eye and can be quantified by visible absorption spectroscopy. Therefore, the method of Reichert et al. anticipates the presently claimed invention.

Response to Arguments

7. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Reichert et al. (*J. Am. Chem. Soc.*, **1995**, 117:829-830) for claims 1-2 and 9-13 were considered but they are not persuasive for the following reasons.

Applicant contends that "[T]he technique of Reichert et al. relies upon a change in color, not a measurement of a change in fluorescence". And "Reichert et al. do not refer to the pink or

orange color as being the non-fluorescent form. In fact, a pink or orange colored polydiacetylene is generally a fluorescent form of the polydiacetylene". Thus the method of Reichert et al. does not anticipate the presently claimed method.

Applicant's arguments are not convincing since the method of Reichert et al. does anticipate the presently claimed method. Although Reichert et al. do not refer to the pink or orange color as being the non-fluorescent form, Reichert et al. do disclose that "[T]he conjugated backbone of alternating double and triple bonds gives rise to intense absorptions in the visible spectrum" (pg. 829, left col., lines 31-33) (e.g. the deep blue or purple colored is the non-fluorescent form of the polydiacetylene). Then when the influenza virus is added to the liposomes change from blue or purple to pink or orange would be a change in fluorescent since applicant has indicated "[a] pink or orange colored polydiacetylene is generally a fluorescent form of the polydiacetylene". Therefore method of Reichert et al. does measure a change in fluorescence and would anticipate the presently claimed method.

Claim Rejections - 35 USC § 103

8. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al. (US Patent 5,415,999) and Charych et al. (US Patent 6,180,135 B1).

The presently claimed claims recite a method for detection of an analyte in a sample. The method comprise of contacting the sample with the three-dimensional array. The three-dimensional array comprise of a polydiacetylene backbone and a substrate, wherein the substrate has direct affinity for an analyte. The change in fluorescent of the polydiacetylene of

the array is in response to the analyte present in the sample and detecting the change in fluorescence to indicate the presence of an analyte.

Charych et al. disclosed a method for detection of an analyte in a sample comprising a three-dimensional array of a polydiacetylene backbone and the array is in the form of liposomes or tubules (Abstract; col. 4, line 24-33; col. 8, line 63-64). The liposomes comprised of polydiacetylene, which has a conjugated backbone of alternating double and triple bonds (col. 4, lines 25-29), and ligand (col. 10, lines 7-37). The liposomes produced by either of the process of claim 1 or 22 of Charych et al. are the same as those of instant claim 1 with the exception that the array of the instant claim is fluorescent in nature while that of Charych et al. is colorimetric in nature.

The method of Charych et al. differs from the claimed invention in failing to disclose the fluorescent detection of the polydiacetylene backbone.

Saul et al. disclosed a method for detection of an analyte in a sample (Abstract). The method comprises the use of a polydiacetylene backbone (col. 2, line 61-67; claim 1 and 6). A substrate incorporated is in an array (col. 3, line 10-15). The substrate has direct affinity for the analyte or can function as a binder to the analyte or can react with the analyte (claim 1(a), col. 14, line 21-32; col. 3, line 34-39). Detecting the change in fluorescence is used to indicate the presence of the analyte (col. 3, line 25-29; claim 1(b), line 32-33). The analyte is an enzyme, antigen, antibody or antibody fragment and the substrate is a specific binding pair member of the analyte (col. 2, line 44-47; col. 6, line 9-21, and 67-68 and continue to col. 7, line 1-6; col. 10, line 5-24). The substrate includes a ligand (col. 3, line 34-35 and 40-42). The substrate includes

a reactive substrate (col. 6, line 9-14). The polydiacetylene of the array exhibits fluorescence and the fluorescence increases as an indication of the presence of the analyte (col. 8, line 18-28).

The teaching of both Charych et al. and Saul et al. demonstrate that both colorimetric and fluorescent detection methods are well known for use with analytical methods which use polydiacetylene films (Charych: col. 2, line 59 through col. 3, line 5; Saul: col. 2, line 61-67; claim 1 and 6) it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ***colorimetric*** method of detection of the ***"polydiacetylene"*** of Charych et al. by including the ***fluorescent*** method of detection of the ***"polydiacetylene"*** as taught by Saul et al. with the expectation of obtaining an equivalent method of direct detection of small molecules using a three dimensional polymeric assemblies and a test system that can be suspended in fluid or bound to various supports (Charych: col. 3, line 29-39).

Response to Arguments

9. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Saul et al. (US Patent 5,415,999) and Charych et al. (US Patent 6,180,135 B1) for claims 1-19 were considered but they are not persuasive for the following reasons.

Applicant alleges that the combination of Saul et al. and Charych et al. is not obvious over the presently claimed method because the method of Saul et al. "[r]equires a red, fluorescent, polydiacetylene film and a separate fluorescence modulation reagent" and Charych et al. does not "[s]uggest that the three-dimensional array could be used in the method that detects the change in fluorescence".

Applicant's arguments are not convincing since the combination of Saul et al. and Charych et al. is obvious over the presently claimed method. First the "comprises" terminology

of the instant claim 1 is open-ended and does not exclude possible additional elements such as the fluorescence modulation reagent described by Saul et al. Second the change in fluorescence in the method of Saul et al. is due to the binding of the analyte (col. 8, lines 23-28). The method of Charych et al. does suggest detecting a change in fluorescence (e.g. a change from blue to red (col. 4, lines 28-32)). The blue color is the non-fluorescence form of polydiacetylene film (Charych: col. 4, lines 28-32) and the red color is the fluorescent form of the polydiacetylene film (Saul: col. 2, line 61-67; claim 1 and 6). Thus a change from blue to red is a change in fluorescence. Therefore the combination of Saul et al. and Charych et al. is obvious over the presently claimed method.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

mct
October 20, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER